

Remarks

After entry of this Amendment, the pending claims are claims 1-68, with claims 9-12, 22, 26 and 32-50 withdrawn from consideration at this time. The Applicant would like first to thank the Examiner for indicating the allowance of the subject matter of claims 15, 23 - 25 and 27. The Office Action dated November 21, 2003 has been carefully considered. Claims 1, 13 - 18, 23 and 28 have been amended. New claims 51 - 68 have been added to more particularly point out and distinctly claim the subject matter of the invention. Support for these new claims can be found in the specification and claims as originally filed. No new matter has been added.

Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated November 21, 2003, the Examiner:

- withdrew claims 9-12, 22, 26 and 32-50 from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to nonelected inventions and species.
- rejected claims 1-7, 13-21, 23-25 and 27-31 under 35 U.S.C. 112(2) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 1, "the spinal column," lacked a prior antecedent; in claim 13, "the intermedullary canal of the donor bone," lacked a prior antecedent; in claim 14, "the intermedullary canal of the donor bone," lacked a prior antecedent; in claim 23, "the spinal column," lacked a prior antecedent.
- rejected claims 1-3, 6, 7, 13, 14 and 18 under 35 U.S.C. 102(b) as being anticipated by WO 00/38461 to Paul et al. ("the Paul PCT application");
- rejected claims 1, 2, 5, 6 and 18-20 under 35 U.S.C. 102(e) as being anticipated by United States Patent No. 6,039,762 to McKay ("the McKay patent");
- rejected claims 1, 2 and 16-21 under 35 U.S.C. 102(a) as being anticipated by JPO2000175943 to Yonenobu et al. (the "Yonenobu reference");
- rejected claims 4, 5, 8, 20, 21 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over the Paul PCT application;

- rejected claims 3, 4, 7, 8, 13, 14, 16, 17, 21 and 28-31 under 35 U.S.C. 103(a) as being unpatentable over the McKay patent;
- rejected claims 3-8, 13, 14, 21 and 28-31 under 35 U.S.C. 103(a) as being unpatentable over the Yonenobu reference;
- indicated claim 15 as allowable if rewritten to overcome the rejections under 35 U.S.C. 112(2), set forth in the Office Action, and to include all of the limitations of the base claim and any intervening claims;
- indicated claims 23-25 and 27 as allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112(2), set forth in the Office Action.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Independent Claims 1 and 23

Independent claims 1 and 23 were rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claims 1 and 23, "the spinal column," lacked a prior antecedent. Claims 1 and 23 have been amended to recite, *inter alia*, an implant for use in a patient's spinal column. Applicants respectfully submit that there is sufficient antecedent bases for all terms in claims 1, 23 and their dependent claims.

Dependent Claims 13 and 14

Dependent claims 13 and 14 were rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claims 13 and 14, "the intermedullary canal of the donor bone," lacked prior antecedent. Claim 13 has been amended to recite, *inter alia*, the implant of claim 7 wherein the bone allograft material is obtained from a cross-section of a donor bone having an intermedullary canal, and wherein said inner surface of the implant is defined by the intermedullary canal of the donor bone. Claim 14 has been amended to depend upon claim 14, instead of claim 7. Applicants respectfully submit that there is sufficient antecedent bases for all terms in claims 13, 14, and their dependent claims

Claim Rejections - 35 U.S.C. § 102**Independent Claim 1****The Paul PCT Application**

Independent claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by the Paul PCT application. Independent claim 1 has been amended to recite, *inter alia*, an implant comprising a body portion having a length, a width and a depth, and configured to be insertable between first and second cut bone segments of a single vertebra, the body portion having an outer surface, and an inner surface configured to render the body portion substantially hollow, the body portion further having first and second ends which communicate with said inner surface, the first and second ends comprising bone engaging portions each having a length; wherein at least one of the bone engaging portions comprises a bone receiving channel that extends a substantial portion of the length of the bone engaging portion, the channel configured and adapted to engage and retain at least one of the first and second cut bone segments.

Correspondingly, claims 15 - 18, which depend from claim 1, have been amended to recite "bone receiving channel(s)," in lieu of "cutout(s)," to conform with the above amendment to independent claim 1.

Applicants respectfully submit that the Paul PCT application does not disclose, teach or suggest all of the limitations of claim 1. Specifically, there is no disclosure, teaching or suggestion in the Paul PCT application of an implant ... configured to be insertable between first and second cut bone segments of a single vertebra. Rather, the spacer of the Paul PCT application is configured for use in an intervertebral fusion procedure in which two adjacent vertebral bodies are fused together by removing the intervertebral disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc material. (*See* Paul PCT, p.1, paragraphs 2-3). Thus, it is respectfully submitted that the Paul PCT application does not disclose, teach, or suggest all of the limitations of independent claim 1. It is respectfully submitted that independent claim 1 is thus allowable over the Paul PCT application. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 2-8 and 13-21, which depend from claim 1, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 1, they are also patentably distinguished over the Paul PCT application for at least the same reasons as identified with respect to claim 1.

The McKay patent

Independent claim 1 was rejected under 35 U.S.C. 102(e) as being anticipated by the McKay patent. Independent claim 1 has been amended as indicated above in relation to the discussion of the Paul PCT application. Applicants respectfully submit that the McKay patent does not disclose, teach or suggest all of the limitations of claim 1. Specifically, there is no disclosure, teaching or suggestion in the McKay patent of an implant comprising a body portion ... configured to be insertable between first and second cut bone segments of a single vertebra. Like the Paul implant, the McKay patent discloses an implant 10 including a body 11 sized and configured for engagement between two vertebrae. (See McKay patent, 4:25-33 and Figure 3).

Further, applicants submit that there is no disclosure, teaching or suggestion in the McKay patent of an implant ... comprising a body portion ... having first and second ends ... the first and second ends comprising bone engaging portions each having a length; wherein at least one of the bone engaging portions comprises a bone receiving channel that extends a substantial portion of the length of the bone engaging portion, the channel configured and adapted to engage and retain at least one of the first and second cut bone segments. Rather, the McKay patent discloses an implant 10 having attaching means for attaching the sleeve 21, 31 of the implants to the adjoining vertebral bodies V, and the attaching means can be teeth 23 disposed at the superior 26 and inferior 27 ends of the sleeve 21. (See McKay patent, 6:42-47 and Figures 3 and 4). The attachment means may alternatively include roughened surfaces 33, 34 defined on the superior 26 and inferior 27 ends of the sleeve. (See *id.* at 6:47-52).

It is respectfully submitted that independent claim 1 is thus allowable over the McKay patent. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 2-8 and 13-21, which depend from claim 1, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 1, they are also patentably distinguished over the McKay patent for at least the same reasons as identified with respect to claim 1.

The Yonenobu Reference

Independent claim 1 was rejected under 35 U.S.C. 102(a) as being anticipated by the Yonenobu reference. Independent claim 1 has been amended as indicated above in relation to the discussion of the Paul PCT application. Applicants respectfully submit that the Yonenobu reference does not disclose, teach or suggest all of the limitations of claim 1. For

example, there is no disclosure, teaching or suggestion in the Yonenobu reference of an implant comprising a body portion ... the body portion having an outer surface, and an inner surface configured to render the body portion substantially hollow. While the Yonenobu spacer does have a penetrating hole 17 through which suture material is passed, (*see* Yonenobu reference translation at para. 7), this penetrating hole does not render the Yonenobu spacer "substantially hollow." Rather, even with the penetrating hole, the Yonenobu spacer remains substantially solid. Thus, it is respectfully submitted that the Yonenobu reference does not disclose, teach, or suggest all the limitations of independent claim 1.

It is respectfully submitted that independent claim 1 is thus allowable over the Yonenobu reference. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 2-8 and 13-21, which depend from claim 1, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 1, they are also patentably distinguished over the Paul PCT application for at least the same reasons as identified with respect to claim 1.

Claim Rejections - 35 U.S.C. § 103

Independent Claim 28

The Paul PCT Application

Independent claim 28 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of the Paul PCT application. Independent claim 23 has been amended to recite, *inter alia*, an implant for use in a laminoplasty procedure, the implant comprising a body portion ... insertable between first and second bone segments of a single vertebra, the body portion having first and second ends, at least one of the first and second ends comprising a bone engaging portion to engage at least one of the first and second bone segments, wherein at least one of the first and second bone engaging portions is comprised of demineralized allograft material. Applicants respectfully submit that the Paul PCT application does not disclose, teach or suggest all of the limitations of claim 28. Specifically, the Paul PCT application does not disclose, teach or suggest an implant comprising a body portion ... insertable between first and second bone segments of a single vertebra. As discussed in relation to claim 1, the spacer of the Paul PCT application is configured for use in an intervertebral fusion procedure in which two adjacent vertebral bodies are fused together by

removing the intervertebral disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc material. (See Paul PCT, p.1, paragraphs 2-3). Thus, it is respectfully submitted that the Paul PCT application does not disclose, teach, or suggest all of the limitations of independent claim 1.

It is respectfully submitted that independent claim 28 is thus allowable over the Paul PCT application. Withdrawal of this rejection and allowance of independent claim 28 is respectfully requested. With respect to claims 29-31, which depend from claim 28, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 28, they are also patentably distinguished over the Paul PCT application for at least the same reasons as identified with respect to claim 28.

The McKay Patent

Independent claim 28 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of the McKay patent. Independent claim 28 has been amended as indicated above in relation to the discussion of the Paul PCT application. Applicants respectfully submit that the McKay patent does not disclose, teach or suggest all of the limitations of claim 28. Specifically, there is no disclosure, teaching or suggestion in the McKay patent of an implant comprising a body portion ... configured to be insertable between first and second bone segments of a single vertebra. Like the Paul implant, the McKay patent discloses an implant 10 including a body 11 sized and configured for engagement between two vertebrae. (See McKay patent, 4:25-33 and Figure 3).

It is respectfully submitted that independent claim 28 is thus allowable over the McKay patent. Withdrawal of this rejection and allowance of independent claim 28 is respectfully requested. With respect to claims 29-31, which depend from claim 28, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 28, they are also patentably distinguished over the McKay patent for at least the same reasons as identified with respect to claim 28.

The Yonenobu Reference

Independent claim 28 was rejected under 35 U.S.C. 103(a) as being unpatentable in view of the McKay patent. Independent claim 28 has been amended as indicated above in relation to the discussion of the Paul PCT application. Applicants respectfully submit that the McKay patent does not disclose, teach or suggest all of the limitations of claim 28. Specifically, the Yonenobu reference does not disclose, teach or suggest an implant

comprising a body portion ... insertable between first and second bone segments ... the body portion having first and second ends, at least one of the first and second ends comprising a bone engaging portion to engage at least one of the first and second bone segments, wherein at least one of the first and second bone engaging portions is comprised of demineralized allograft material. To the contrary, the Yonenobu reference specifically teaches away from using allograft material as a spacer material, and states the undesirability of using bone as a graft materials. (See Yonenobu reference translation at para. 3, stating "... bone grafts from the ilium or spinous process are absorbed over time, making the maintenance of the degree of expansion impossible. See also Yonenobu at para. 19, stating "artificial materials are used, so the absorption associated with natural bone does not occur").

Thus, it is respectfully submitted that independent claim 28 is allowable over the Yonenobu reference. Withdrawal of this rejection and allowance of independent claim 28 is respectfully requested. With respect to claims 29-31, which depend from claim 28, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 28, they are also patentably distinguished over the Yonenobu reference for at least the same reasons as identified with respect to claim 28.

New Dependent Claims 51 and 52

New claims 51 and 52 have been added to more particularly point out and distinctly claim the invention of claim 23, from which they depend.

New Independent Claim 53, and Dependent Claims 54-68


New independent claim 53 comprises original claim 15 rewritten in independent form, including all of the limitations of the base claim. Original claim 15 has already been indicated as allowable by the examiner as such. Applicants respectfully submit that dependent claims 54-68 are also allowable because these claims define more particular aspects of the applicant's invention as well as including the features of claim 53.

In light of applicants' amendments and remarks, a notice of allowance is respectfully requested. Should the examiner have any questions or concerns regarding the amendments, remarks or the above-identified application, then a telephonic interview with the undersigned is respectfully requested to discuss any such questions or concerns and to accelerate the allowance of the above-identified application.

Applicants estimate that due to the addition of one new independent claim 54, and new dependent claims 52-53 and 55-68, a fee of \$410 is required for this Amendment. An appropriate Fee Transmittal Form is enclosed. Any additional fees should be charged to Jones Day Deposit Account No. 16-1150.

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Respectfully submitted,


By: Jeffrey M. Chamberlain P55,044
(Reg. No.)

35,340
For: Brian M. Rothery (Reg. No.)
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939